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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,871	01/06/2004	Stephen Donovan	17359CON2CIP1CIP1 (BOT)	4854

7590 02/08/2008

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EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/752,871	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Effective Filing Date/Amendment

Applicant has amended the claims to generically claim "an implant for treating a condition of an eye" instead of an ocular implant.

Applicant states that there is support for treating conditions of the eye using an implant from the grandparent application, and points out the disclosure of "strabismus," which is a condition of the eye. Note is made of the disclosure of "strabismus" in the discussions concerning the *prior art*. Applicant describes the condition in column 4, line 47 and column 8, lines 1-6 of the '423 patent, as being previously treated with intramuscular injection of botulinum. Applicant's '423 patent is dedicated to providing an implant in place of the injection to provide a longer term medication of the muscle.

To this end, applicant states the implant can be planted in the "vicinity" of the targeted muscle group (column 11, line 35 of the '423 patent), however, "local administration" is defined as "subcutaneous, intramuscular, intraspinal (i.e. intrathecal and epidural), intracranial, and intraglandular administration" at column 13, lines 50-55 of '423. Additional implant methods are described in column 14, lines 26-40; column 22, lines 48-55 of '423. None of these concern providing an implant into "a location in the eye" as claimed in applicant's current claims 10-12, or "into the vitreous cavity of an eye" as recited in claim 13. Accordingly, claims 10-13, dedicated to implants into a location in the eye, are not supported by applicant's previous applications.

It is agreed that applicant's discussion of the prior art injections to treat strabismus in the '423 patent, and applicant's disclosure of intramuscular implants in

place of injections in the '423 patent, provide support for an intramuscular implant to treat strabismus. Accordingly, claims 1, 4, 5 and 8, dedicated to a generic "implant" for treating the eye, which now do not recite that the implant is an "ocular implant", do have support from the parent applications as currently presented with the new amendment.

Terminology is interpreted according to the normal usage. An "ocular implant" is an implant inserted into the eye as is known in the art, which is contrasted to an injection of an implant into the eye region, for example, an intramuscular eye region. The term "implant" is interpreted as the normal meaning. It is a solid object placed in the body, surgically or otherwise. A "carrier" is interpreted according to the normal meaning, and can include a solvent used to simply dissolve a therapeutic agent. Applicant's claim 1 still requires an "implant" which is distinguished from a "carrier" but can include a "carrier."

Regarding claims 2, 3, 6, 7, these claims require specific ranges of therapeutic, and this information is not found in applicant's previous applications. Further, the specific ocular conditions recited in claim 9 have not been found in the parent applications.

In summary, the examiner takes the position that claims 1, 4, 5 and 8, as amended, find support from applicant's parent applications, however, the remaining claims do not.

Double Patenting

In view of applicant's broadened claims, double patenting rejections are now appropriate.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, 19 of U.S. Patent No. 6,306,423. Although the conflicting claims are not identical, they are not patentably distinct from each other because nothing precluded applicant from claiming the implant for the eye as is now claimed.

Claims 1, 4, 5 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-15, 18 of U.S. Patent No. 6,383,509. Although the conflicting claims are not identical, they are not patentably

distinct from each other because nothing precluded applicant from claiming the implant for the eye as is now claimed.

Claims 1, 4, 5 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,585,993. Although the conflicting claims are not identical, they are not patentably distinct from each other because nothing precluded applicant from claiming the implant for the eye as is now claimed.

Claims 1, 4, 5 and 8 are rejected on the ground of nonstatutory provisional obviousness-type double patenting as being unpatentable over claims 1-13, 18-21 of U.S. Serial No. 10/445,142, claim version 06/11/2007. Although the conflicting claims are not identical, they are not patentably distinct from each other because nothing precluded applicant from claiming the implant for the eye as is now claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Abreu '313. These claims are again rejected. See the comments set forth in the previous office action and above regarding the effective filing date of these claims.

Claims 1, 4, 5, 8 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Singh et al., US 6,994,859. Regarding claim 1, Singh discloses a composition comprising Hn-33, which is a biologically active, protease resistant hemagglutinin isolated from Clostridium botulinum neurotoxin, in combination with at least one neurotoxin, e.g., type A or E botulinum neurotoxin. See especially column 1, line 53 to column 2, line 10. Therapeutic compositions are disclosed in column 11. Note that various disorders including strabismus are disclosed. Therapeutic carriers are disclosed in column 11, lines 21-47. Regarding claim 4, see column 11, line 41.

Claim 10 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Singh '859. Singh discloses the treatment of strabismus as discussed above, claim 10 recites all of the reasonable locations for insertion of a biodegradable implant into the eye. Singh does not disclose a location. The examiner takes the position that it is inherent that Singh intends at least one of these locations, since the claimed locations encompass most of the entire eye, or in the alternative, it would be obvious to one of ordinary skill in the art to insert the Singh implant into one of the recited regions of the eye to inhibit the specific muscles causing the spasms contributing to strabismus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 6, 7, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu '313. See the comments set forth in the previous office action and above regarding the effective filing date of these claims. Regarding claims 12, and 13, applicant argues that the 10-fold concentration difference found in the vitreous cavity as opposed to the aqueous humor of the eye is novel and not suggested, however, Abreu discloses the same implant, preferably located in the vitreous cavity. It seems inherent that the Abreu concentration would be 10 times as much in the vitreous cavity as compared to the aqueous humor. If applicant wants to pair a structurally significant aspect of the implant with the function recited, this would be convincing, or at least point out why this is unique or unexpected.

Response to Arguments

Applicant's arguments filed November 15, 2007 have been fully considered but they are not persuasive. Applicant's claim amendment has removed the Abreu '313 patent as a reference against claims 1, 4, 5 and 8, however, the Singh et al. '859 anticipates these claims and is now applied in view of the amendment. Applicant may

note that Singh '859 has a relationship to applicant's cited WO 99/37326, however, the examiner used the U.S. Patent for convenience. The WO '326 has an earlier publication date, but is still a 102(e)-type reference in view of applicant's June 2, 2000 grandparent filing date. However, the WO '326 may qualify as a 102(b)-type reference as applicant presents claim amendments, and applicant should keep these various dates in mind.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/
Sharon E. Kennedy
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Art Unit 1615